

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG,	)	
ABBOTT BIORESEARCH CENTER, INC.,	)	C.A. No. 4:09-CV-11340 (FDS)
and ABBOTT BIOTECHNOLOGY LTD.,	)	
	)	
Plaintiffs,	)	JURY TRIAL DEMANDED
	)	
v.	)	<b>PUBLIC REDACTED VERSION</b>
	)	
CENTOCOR ORTHO BIOTECH, INC. and	)	
CENTOCOR BIOLOGICS, LLC.,	)	
	)	
Defendants.	)	

**CENTOCOR'S DAUBERT MOTION TO EXCLUDE TESTIMONY  
OF ABBOTT EXPERT JOAN ELLIS  
AND MEMORANDUM IN SUPPORT**

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The Centocor Defendants (“Centocor”) hereby move to exclude from evidence the opinion testimony of Abbott patent expert, Joan Ellis, on the issue of priority of invention. Ms. Ellis’ opinion is unreliable as it is based on erroneous legal underpinnings. In addition, Ms. Ellis, as a patent expert, possesses no expertise by knowledge, skill, experience, training, or education that qualifies her to opine on priority of invention. Her opinion on priority fails to reach the threshold of admissibility under Federal Rule of Evidence 702 and should be excluded.<sup>1</sup>

## I. INTRODUCTION

Centocor contends that the Abbott patent claims asserted against it are invalid under 35 U.S.C. 102(g)(2) because the invention recited in those claims was made earlier by Centocor inventors. Centocor contends that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (D.I. 221 at 8-9). “The parties agree that [Centocor inventor] Ms. Giles-Komar recognized and appreciated that ustekinumab was a human neutralizing antibody to IL-12 no later than April 30, 1998” (D.I. 341 at 61). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Court denied Centocor’s motion for summary judgment that Abbott’s claims are invalid because of Centocor’s prior invention, finding that there is a dispute of fact with respect

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<sup>1</sup> Ms. Ellis’ report contains other opinions and proposed testimony that are objectionable on non-*Daubert* grounds (for example, testimony regarding the law); however, Centocor anticipates that its objections to that testimony may be overcome by meeting and conferring with Abbott prior to the deadline for filing *in limine* motions. This motion, therefore, addresses only *Daubert*-type grounds for limiting Ms. Ellis’ testimony.

to the date of *Abbott's* invention (D.I. 341 at 61, 63). Thus, the question of priority of invention will be presented to the jury.

Abbott submitted an expert report for Joan Ellis, a patent attorney and former patent examiner and Administrative Patent Judge at the U.S. Patent and Trademark Office (Ex. 1, Ellis Rpt). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(*Id.* at ¶98, emphasis added). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Ex. 2, Ellis Dep. at 144:18-145:22; *see also id.* at 134:23-135:22).

Ms. Ellis based this opinion on an error of law. According to Ms. Ellis, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This is wrong. And since this error of law is the cornerstone of Ms. Ellis' opinion, that opinion is unreliable and should be excluded.

Even if her opinion was not contrary to law, Ms. Ellis should still not be permitted to testify on the issue of prior invention because, as a patent attorney, she has no particular qualifications or specialized knowledge that qualify her to render her opinion.

## **II. APPLICABLE LEGAL STANDARDS FOR ADMISSIBILITY OF EXPERT TESTIMONY**

Fed. R. Evid. 702, which governs the admissibility of testimony by expert witnesses, provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702 (2011).<sup>2</sup>

The court acts as a "gatekeeper" under Rule 702, testing whether scientific evidence is "not only relevant, but reliable." *Daubert v. Merrill Dow Pharm.*, 509 U.S. 579, 589 (1993). The court should "make certain that an expert, whether basing testimony on professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526

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<sup>2</sup> The wording of Rule 702 was amended in 2011 but, according to the Committee Notes on the 2011 amendment, the "changes are intended to be stylistic only" and "[t]here is no intent to change any result in any ruling on evidence admissibility." Fed. R. Evid. 702 advisory committee's note (2011 Amendments).

U.S. 137, 152 (1999). “Under Daubert, ‘any step that renders the analysis unreliable . . . *renders the expert’s testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.*’” *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 670-671 (5th Cir. 1999) (emphasis in original) (citations omitted). *See also Apple, Inc. v. Motorola, Inc.*, No. 1:11-cv-08540, 2012 WL 195960, at \*1-2 (N.D. Ill. May 22, 2012) (Ex. 3).

“Two gateposts frame the exercise of a judge’s discretion to admit or exclude expert testimony.” *Albert v. Warner-Lambert Co.*, 234 F.Supp.2d 101, 104 (D. Mass. 2002). First, the expert witness must be shown to be sufficiently qualified by “knowledge, skill, experience, training, or education.” *Id.* (quoting Fed. R. Evid. 702). Second, it must be “ensure[d] that any and all scientific testimony or evidence admitted is not only relevant, but [also] reliable.” *Id.* (quoting *Daubert*, 509 U.S. at 589).

“In *Daubert*, the Supreme Court set forth four general guidelines for a trial judge to evaluate in considering whether expert testimony rests on an adequate foundation: ‘(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique’s known or potential rate of error; and (4) the level of the theory or technique’s acceptance within the relevant discipline.’” *Beaudette v. Louisville Ladder, Inc.*, 462 F.3d 22, 25 (1st Cir. 2006) (citations omitted). These factors, however, do not “constitute a definitive checklist or test” as the question of admissibility “must be tied to the facts of a particular case.” *Kumho Tire*, 526 U.S. at 150 (quotations omitted).

“Although the approach is flexible by its nature . . . , an overarching concern is on the ‘evidentiary relevance and reliability’ of the proposed testimony.” *Seahorse Marine Supplies, Inc. v. Puerto Rico Sun Oil Co.*, 295 F.3d 68, 81 (1st Cir. 2002) (quoting *Daubert*, 509 U.S. at 595). The Court has “considerable leeway” in both “how to determine reliability” and “its

ultimate conclusion” on this gate-keeping matter. *Kumho Tire*, 526 U.S. at 152-53. Importantly, “[t]he burden of persuading the judge to allow the expert to testify is on the party tendering the expert, and is by a preponderance of the evidence.” *Apple*, 2012 WL 1959560, at \*1 (citing, *inter alia*, *Daubert*, 509 U.S. at 592 n.10) (Ex. 3).

### **III. MS. ELLIS’ OPINION ON PRIORITY SHOULD BE EXCLUDED**

#### **A. Ms. Ellis’ Opinion Should Be Excluded As It Is Predicated On An Erroneous Legal Premise**

##### **1. To Prove Prior Invention/Reduction to Practice, the Law Does Not Require that the Prior Inventors Appreciate That Their Invention Possess Every Element of the Patent Claims**

To prove priority of invention for any of Abbott’s asserted antibody claims by proving an actual reduction to practice, Centocor is required to show that its inventors made an antibody meeting all limitations of the claims, and that they determined that the antibody would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Abbott contends that Centocor’s Stelara antibody meets each and every one of the limitations of the asserted patent claims. And, as the Court noted in its Summary Judgment Order, the parties agree that, no later than April 30, 1998, Centocor’s inventors recognized and appreciated that Stelara (ustekinumab) was a human neutralizing antibody to IL-12 (D.I. 341 at 61). Centocor proved everything it needed to, to establish its April 30, 1998 invention date.

Ms. Ellis, however, contends that Centocor did not meet its burden of proof because it did not prove that the Centocor inventors *appreciated* that the Stelara antibody possessed every limitation of the patent claims. But, contrary to Ms. Ellis’ report and opinion, the Federal Circuit has recognized that, in the context of Section 102(g) prior invention, a prior inventor need not always have appreciated every feature recited in a patent claim in order to have conceived of or reduced to practice the claimed invention.

For example, in *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434-36 (Fed. Cir. 1988), the Federal Circuit held that a defendant in an infringement action could meet its burden to show invalidity under §102(g) by proving that its researchers' earlier-made products possessed certain property limitations of the asserted patent claims, *without also showing that the researchers were aware that their products possessed the properties.* The patent claims at issue in the case related to various copolymers, and as to four of the six claims at issue, the plaintiff had conceded that the defendant's researchers had made the claimed copolymers before the plaintiff had. *Id.* at 1434 & n.3. The remaining two claims included certain property limitations not present in the other four, and as to those claims, the court remanded the case for a determination “whether the claimed copolymer, as defined in part by various property parameters, [was] new.” *Id.* at 1436. The court observed that, as the party challenging validity, the defendant would have the burden on remand to prove that the property limitations were possessed by its researchers' products, but stated that in meeting that burden, the defendant “*need not prove awareness* by [its] researchers that their products possessed the properties.” *Id.* (emphasis added).

Similarly, in *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 748 F.Supp.2d 453 (E.D. Pa. 2010), the issue was whether AstraZeneca's CRESTOR product, if it met the limitations of Teva's patent claims, was invented first, so as to invalidate Teva's claims. The patent claims at issue recited a stabilized pharmaceutical composition that included a “stabilizing effective amount” of an amido compound. *Id.* at 461 n.14. It was not disputed that AstraZeneca's prior CRESTOR formulation met that limitation, but Teva argued that AstraZeneca had not proven prior reduction to practice because its inventors had not appreciated that the amido compound

contributed to the stability of the formulation. *Id.* at 463. The court rejected this argument, noting that:

[A prior] inventor need not “establish that he recognized the invention in the same terms as those recited in the [claims]” as “[t]he invention is not the language of the claims but the subject matter thereby defined.” *Sylvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974); *see also Mycogen Plant Science*, 243 F.3d at 1336 (“The reduction to practice test does not require *in haec verba* appreciation of each of the limitations of the count.”). Rather, the inventor must establish that he recognized and appreciated “a compound corresponding to the compound defined by the [claims].” *Sylvestri*, 496 F.2d at 599.

*Id.* at 466. Indeed, the law is clear that “a [prior art] reference may anticipate even when the relevant properties of the thing disclosed were not appreciated at the time.” *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363, 1367 (Fed. Cir. 2006).

The case law on which Ms. Ellis relies, *Estee Lauder, Inc. v. L’Oreal S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997), is not to the contrary and does not support the misstatement of the law underlying her opinion. (See Ex. 1, Ellis Rpt at ¶¶35, 86). In *Estee Lauder*, the court addressed the issue of an inventor’s proof of reduction to practice by actually preparing a composition and knowing that it would work for its intended purpose. The court held that, when testing is required to show that a composition is useful, the inventors must recognize the successful testing before there can be a reduction to practice. *Estee Lauder*, 129 F.3d at 594-95. The court did *not* hold that the inventors must have appreciated that a composition possessed each of the limitations of a patent claim before they can claim a reduction to practice of that invention.

In sum, Ms. Ellis’ priority opinion is predicated on an error of law.

## **2. The Law Supports Exclusion of Ms. Ellis’ Opinion**

“Expert opinions that are contrary to law are inadmissible.” *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794, 806 (N.D. Ill. 2005). *See also United States v. Wintermute*, 443 F.3d 993, 1001 (8th Cir. 2006) (“Schott’s proffered testimony misrepresented

the government's burden of proving materiality, and by misconstruing the legal question at issue, the testimony was not relevant."); *Bailey v. Allgas, Inc.*, 148 F. Supp. 2d 1222, 1245-46 (N.D. Ala. 2000) (expert's opinion, based on methodology that is contrary to the law, inadmissible under Fed. R. Evid. 702); *Southard v. United Regional Health Care System, Inc.*, No. 7-06-CV-11-L, 2008 WL 4489692, at \*2 (N.D. Tex. 2008) (Ex. 4) ("Although a qualified expert is not necessarily prohibited from expressing an opinion on an ultimate issue of fact, whereas here, the expert's opinion is based on an erroneous legal premise, it is appropriate to exclude such testimony.").

Because Ms. Ellis' priority opinion is based on an erroneous legal premise, it should be excluded.

### **3. Ms. Ellis' Opinion on Priority of Invention Should Also Be Excluded Because Her Testimony Will Not Be Helpful to the Jury**

An additional or alternative reason for excluding Ms. Ellis' opinion on priority is that she has no particular qualifications or specialized knowledge that qualify her to render her opinion. Ms. Ellis has spent her career as a patent attorney (Ex. 1, Ellis Rpt at Ex. A). The question of priority of invention will be decided by the jury by considering the parties' evidence of when their inventors' isolated antibodies and appreciated their usefulness, in view of legal instructions provided by the Court. Ms. Ellis' experience as a patent attorney does not qualify her as an expert for the purposes of rendering an opinion on the sufficiency of Centocor's priority evidence. *See Hem, Inc. v. Behringer Saws, Inc.*, No. 00-CV-0331-EA (J), 2002 WL 34698060, at \*2 (N.D. Okla. 2002) (Ex. 5) ("Patent attorneys may be eminently qualified to speak to matters bearing upon the patenting process, the workings of the U.S. Patent and Trademark Office, and the duties of a patent attorney. However, whether a patent attorney can offer more expansive testimony depends upon the particular patent attorney's education, experience, and training.").

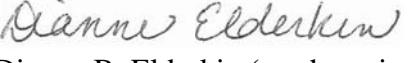
Moreover, it is not an attorney's role to testify as to matters of law. *See Bausch & Lomb, Inc. v. Alcon Labs, Inc.*, 79 F.Supp.2d 252, 255 (W.D.N.Y. 2000) ("Simply put, testimony that is designed to instruct the jury on the applicable law is not admissible because, by purporting to do what lies with the exclusive province of the court, it cannot be helpful to the jury.")

Ms. Ellis' testimony regarding priority of invention will not be helpful to the jury, and, for this additional or alternative reason, it should be excluded.

#### IV. CONCLUSION

For the foregoing reasons, the Court should exercise its gatekeeping authority under *Daubert* and exclude Ms. Ellis' opinion on priority of invention. Her opinion is based on an erroneous legal premise and is, accordingly, unreliable. In addition, Ms. Ellis' opinion would not be helpful as she possesses no expertise by knowledge, skill, experience, training, or education that qualifies her to opine on priority of invention.

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**CERTIFICATION OF COMPLIANCE WITH L.R. 7.1(a)(2)**

I certify that Defendants' counsel has conferred in good faith with opposing counsel on the matter set forth herein to resolve or narrow the issue. Counsel were unable to reach agreement.

/s/ Angela Verrecchio  
Angela Verrecchio

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing **Centocor's Daubert Motion To Exclude Testimony Of Abbott Expert Joan Ellis And Memorandum In Support** was electronically mailed to counsel of record on June 29, 2012 through the Court's ECF system.

/s/ Angela Verrecchio  
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